REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed January 27, 2009. Claims 1-35 were pending, claims 1-13, 17 and 18 were previously withdrawn, and claims 14-16 and 19-35 were rejected in view of cited art.[1] By this amendment, claims 15 and 17 are cancelled and claims 14, 16, 18,[2] and 19 are amended. Claims 1-14, 16, and 18-35 are now pending in view of the above amendments.[3]

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

B. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Office Action rejected claims 14-16 and 19-35, claims 14-16 and 21-35, and claims 14 and 23-25 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

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[1] Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

[2] Claim 18 was previously withdrawn. Nonetheless, claim 18 is amended herein so that it is consistent with changes made to claim 14.

[3] Support for the claim amendments and/or new claim(s) can be found throughout the specification and/or drawings as originally filed.

With regard to the rejection of claims 14-16 and 19-35, the Office Action states that the claims are rejected because "instant application's reference to a restenosis-inhibiting moiety is inadequate." (Office Action, pg. 3) In Response, claim 14 is amended herein to recite, in part, "the restenosis-inhibiting moiety being selected from among the group consisting of a radioactive moiety or a neutron-capture moiety used in combination with a radioactive moiety." Moreover, claim 14 further defines the "restenosis-inhibiting moiety" as being "bound to a second member of the specific binding pair with the second member of the specific binding pair being capable of binding to the first member." Applicant respectfully submits that the amendments to claim 14 presented herein are sufficient to address the Examiner's rejection of claims 14-16 and 19-35. Reconsideration of claims 14-16 and 19-35 is respectfully requested.

With regard to the rejection of claims 14-16 and 21-35, the Office Action states that the claims are rejected because "the specification only discloses art to support a single intravascular device, a stent." (Office Action, pg. 4). Applicant respectfully submits that the specification includes many examples of devices that that can be made radioactive after they are inserted into the body. Suitable examples of devices according to the present Application "include but are not limited to stents, coils, shunts, pins, plates, meshes, particles, spheres, vascular grafts, artificial valves, artificial joints, cannulas, orthopedic burs, catheters, electrode leads, filters, needles, prostheses, and patches. (Application, paragraph [0064][4]) The use of the claimed invention with a stent is merely provided as an illustrative example. The methods and apparatuses discussed in detail in the application that can be used to make a stent radioactive after implantation are equally applicable to "coils, shunts, pins, plates, meshes, particles, spheres, vascular grafts, artificial valves, artificial joints, cannulas, orthopedic burs, catheters, electrode leads, filters, needles, prostheses, and patches." Reconsideration of claims 14-16 and 21-35 is respectfully requested.

With regard to the rejection of claims 14 and 23-25, the Office Action states that the claims are rejected because "the linker is not sufficiently and completely disclosed." (Office Action, pg. 5). Claim 14 recites, in part, "an intravascular medical device having a surface and a first member of a specific binding pair immobilized to the surface, wherein the first member of

[4] Paragraph numbers for the present Application used herein refer to U.S. Pat. Pub. No. 2006/0078493.

the specific binding pair includes a biomolecule selected from among the group consisting of protein, nucleic acid, carbohydrate, lipid, RNA, DNA, antibody, antigen, epitope, lectin, receptor, ligand, avidin, streptavidin, biotin, heparin, or protamine [and] a restenosis-inhibiting moiety bound to a second member of the specific binding pair with the second member of the specific binding pair being capable of binding to the first member, wherein the second member of the specific binding pair includes a biomolecule selected from among the group consisting of protein, nucleic acid, carbohydrate, lipid, RNA, DNA, antibody, antigen, epitope, lectin, receptor, ligand, avidin, streptavidin, biotin, heparin, or protamine." Claim 23 recites in part that "the first member is immobilized by creating one or more types of chemical bonds between the first member and the surface." Claim 24 recites, in part, that "the one or more types of chemical bonds are created between a chemical functional group possessed by the first member and a complementary functional group on the surface." Applicant respectfully submits that claims 14, 23, and 24 recite no linker. With respect to the first and second members of the "specific binding pair," Applicant respectfully submits that the specification of the present Application includes abundant examples of first and second members that can be employed in the presently claimed invention. For example, Table 7 describes a number of examples of specific binding pairs, such as lectin (a carbohydrate binding protein) and a carbohydrate, an enzyme (a protein) and a non-cleavable substrate, a DNA/DNA binding pair, and many others; any one of which can be used in the presently claimed invention.

With respect to the "linker" claimed in claim 25, claim 25 is amended herein to recite in part that the "linker" is "attached to the first member in order to provide a flexible linkage between the first member and the surface of the intravascular medical device." Moreover, claim 25 is amended herein to recite, in part, that the "linker" is "selected from among the group consisting of proteins, peptides, amino acids, ribonucleic acids, deoxyribonucleic acids, nucleosides, nucleotides, phospholipids, fatty acyl chains, carbohydrates, monosaccharides, disaccharides, polysaccharides, organic molecules, inorganic molecules, and combinations thereof."

Applicant respectfully submits that the amendments to claim 14 and 25 presented herein are sufficient to address the Examiner's rejection of claims 14 and 23-25. Reconsideration of claims 14 and 23-25 is respectfully requested.

C. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejected claims 14-16, 19-23, and 28-35 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,871,436 (*Eury*) in view of U.S. Patent No. 5,871,437 (*Alt*) and in further view of .U.S. Patent No. 5,873,811 (*Wang*). Applicant respectfully traverses this rejection in view of the amendments and remarks presented herein because the cited references, either alone or in combination, fail to teach or suggest each and every limitation of the cited references.

In accordance with Applicant's understanding, *Eury* discloses a that is "coated with a chelator selected for its bonding affinity with a specific radio isotope." (Abstract). "Just prior to implantation, the [stent] is immersed in a solution of the radioisotope which enables a prescribed amount of such radioisotope to be adsorbed." *Id.* Likewise, *Alt* discloses a stent that is coated with a radioisotope prior to implantation. (See, e.g., Absract). In accordance with Applicant's understanding, *Wang* discloses coating a treatment area in a vessel with a radioactive adhesive or polymeric material to prevent restenosis. (Abstract) Application of the radioactive adhesive can be followed by stent placement. *Id. Wang's* adhesive is, however, configured to adhere to the vessel surface and not to the surface of a stent.

In contrast to the art of record, claim 14 is amended herein to recite, in part, "[a] kit for inhibiting restenosis in a patient vessel." The kit includes "an intravascular medical device having a surface and a first member of a specific binding pair immobilized to the surface . . .; a restenosis-inhibiting moiety bound to a second member of the specific binding pair with the second member of the specific binding pair being capable of binding to the first member . . .; and a perfusion catheter configured for local administration of the restenosis-inhibiting moiety to the intravascular medical device at an implantation site in the patient vessel after implantation of the intravascular medical device." In other words, the "kit" described in claim 14 and the claims that depend thereon present a system where an intravascular medical device that is coated with the "first member of a specific binding pair" can implanted in a patient and then subsequently coated with "a restenosis-inhibiting moiety bound to a second member of the specific binding pair" via "a perfusion catheter configured for local administration of the restenosis-inhibiting moiety to

the intravascular medical device at [the] implantation site in the patient vessel after implantation of the intravascular medical device."

Applicant respectfully submits that *Eury* fails to teach or suggest a kit that includes an intravascular medical device with "a first member of a specific binding pair immobilized to the surface," "a restenosis-inhibiting moiety bound to a second member of the specific binding pair with the second member of the specific binding pair being capable of binding to the first member," and "a perfusion catheter configured for local administration of the restenosis-inhibiting moiety to the intravascular medical device at an implantation site in the patient vessel after implantation of the intravascular medical device," as required in claim 14 and the claims that depend thereon. Moreover, *Eury* neither teaches nor suggest the desirability of coating an intravascular medical device with "a restenosis-inhibiting moiety bound to a second member of [a] specific binding pair" after the intravascular medical device is implanted. In fact, *Eury* teaches the exact opposite in teaching that a stent should be coated with radioactive material *prior* to implantation. Applicant respectfully submits that *Alt* and *Wang* do nothing to address the deficiencies of *Eury* in this regard. *Alt* like *Eury* teaches stents that are coated with radioactive material prior to implantation of the stent. In contrast to the presently claimed invention, *Alt* does not provide a system for coating an intravascular medical device with "a restenosis-inhibiting moiety bound to a second member of [a] specific binding pair" after the intravascular medical device is implanted. And while *Wang* does teach that a *vessel* surface can be coated with a radioactive adhesive or polymeric composition *prior* to implantation of a stent, Applicant respectfully submits that this is not relevant to a system for coating an *intravascular medical device* with a restenosis-inhibiting moiety using specific binding pairs *after* the intravascular medical device has been implanted at a treatment site because *Wang* does not include "a restenosis-inhibiting moiety bound to a second member of the specific binding pair with the second member of the specific binding pair being capable of binding to the first member," as recited in claim 14.

Applicant also respectfully submits that the "kit" claimed herein provides for functional differences that further distinguish the present claimed invention over the art of record. For example, the intravascular medical device included in the claimed "kit" can be recharged with a restenosis-inhibiting moiety (e.g., a radioactive moiety) long after implantation by re-infusing the

area around the implantation site with the a restenosis-inhibiting moiety (See, e.g., Application, paragraph [0053]). The present Application teaches, for example, that "[r]echarging may be desirable according to the knowledge and requirements of the skilled artisan. Usually recharging is desirable if the radioactivity associated with the first administration has substantially decayed, but the restenosis disease process has not been fully inhibited. Recharging can be effected after the second member of the specific binding pair is removed, either actively or via a passive mechanism. Recharging is also possible if first members of the specific binding pair were not saturably bound during the first administration." (Application, paragraph [0313]). Applicant respectfully submits that the cited references, either alone or in combination, neither teach nor suggest that recharging an intravascular medical device with a a restenosis-inhibiting moiety is desirable, nor do the cited references provide means for recharging an intravascular medical device with a restenosis-inhibiting moiety after implantation. And as with Applicant's submission that the teachings of *Wang* are not relevant to coating a stent *after* it is implanted, Applicant submits that the teachings of *Wang* are not relevant to recharging an intravascular medical device (e.g., a stent) with a restenosis-inhibiting moiety after it is implanted.

Based on the foregoing, Applicant respectfully submits that the Office Action has failed to present a *prima facie* case of obviousness because the reference cited references, either alone or in combination, fail to teach or suggest each and every limitation of the rejected claims, as amended herein. As such, Applicant requests the withdrawal of the rejection under 35 U.S.C. § 103(a) and respectfully request reconsideration of claims 14, 16, and 19-23.

D. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner

provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Dated this 18th day of June, 2009.

Respectfully submitted,

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